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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,649	07/09/2003	Judy H. Chiao	24852-501 CIP2	9975
35437	7590	09/08/2006		
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO 666 THIRD AVENUE NEW YORK, NY 10017				
			EXAMINER GRAFFEO, MICHEL	
			ART UNIT 1614	PAPER NUMBER

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/616,649	Applicant(s) CHIAO ET AL.	
	Examiner Michel Graffeo	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-270 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-270 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 6-19 and 34-47 drawn to a method of treating cutaneous T-cell lymphoma, classified in class 514, subclass 675.
- II. Claims 2 and 20-33, drawn to a method of treating cutaneous T-cell lymphoma, classified in class 514, subclass 277.
- III. Claim 3, drawn to a method of treating cutaneous T-cell lymphoma, classified in class 514, subclass 645.
- IV. Claim 5, drawn to a method of treating cutaneous T-cell lymphoma, classified in class 514, subclass 579.
- V. Claims 48, 53-66 and 81-94 drawn to a method of treating peripheral T-cell lymphoma, classified in class 514, subclass 675.
- VI. Claims 49 and 67-80 drawn to a method of treating peripheral T-cell lymphoma, classified in class 514, subclass 277.
- VII. Claim 50, drawn to a method of treating peripheral T-cell lymphoma, classified in class 514, subclass 645.
- VIII. Claim 52, drawn to a method of treating peripheral T-cell lymphoma, classified in class 514, subclass 579.
- IX. Claims 95, 100-114 and 130-144 drawn to a method of treating head and neck cancer, classified in class 514, subclass 675.

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- X. Claims 96 and 115-129 drawn to a method of treating head and neck cancer, classified in class 514, subclass 277.
- XI. Claim 97, drawn to a method of treating head and neck cancer, classified in class 514, subclass 645.
- XII. Claim 99, drawn to a method of treating head and neck cancer, classified in class 514, subclass 645.
- XIII. Claims 145-186, drawn to a method of inducing cell differentiation, classified in class 514, subclass 675.
- XIV. Claims 187-207, drawn to a method of inducing cell growth arrest, classified in class 514, subclass 675.
- XV. Claims 208-228, drawn to a method of selectively inducing apoptosis, classified in class 514, subclass 675.

Inventions I to IV are directed to related species. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs particularly because they involved separate and distinct compounds. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

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Inventions V-VIII are directed to related species. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs particularly because they involved separate and distinct compounds. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions IX to XII are directed to related species. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs particularly because they involved separate and distinct compounds. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions of Groups I to IV are directed to the treatment of cutaneous T-cell lymphoma whereas the inventions of Groups V-VIII are directed to the treatment of peripheral T-cell lymphoma. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different

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design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants.

See MPEP § 806.05(j). In the instant case, the inventions as claimed have different modes of operation and effects because they are directed to different types of cancer.

Particularly, cutaneous T-cell lymphoma is a low grade or indolent form of cancer whereas peripheral T-cell lymphoma is an aggressive form of cancer. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions of Groups I to IV are directed to the treatment of cutaneous T-cell lymphoma whereas the inventions of Groups IX-XII are directed to the treatment of head and neck cancer. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different modes of operation and effects because they are directed to different types of cancer. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions of Groups V-VIII are directed to the treatment of cutaneous T-cell lymphoma whereas the inventions of Groups IX-XII are directed to the treatment of head and neck cancer. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design,

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mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different modes of operation and effects because they are directed to different types of cancer.

Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The invention of Group XIII is directed to the treatment of a different species of cancer than Groups I-XII and Groups XIV or XV. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different modes of operation and effects because they are directed to different types of cancer. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The invention of Group XIV is directed to the treatment of a different species of cancer than Groups I-XIII or XV. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have

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different modes of operation and effects because they are directed to different types of cancer. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The invention of Group XV is directed to the treatment of a different species of cancer than Group XIV. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different modes of operation and effects because they are directed to different types of cancer. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The practice, re: Markush claims encompassing multiple independent and patentably distinct inventions is set forth in M.P.E.P. 803. The following requirement to make a provisional election of a single independent and patentably distinct invention is made pursuant to said practice.

If Applicant elects either Group XIII, XIV or XV, Applicant must further elect a species of patentably distinct compound as set forth below.

Claims 145-186 drawn in Markush format encompass multiple and patentably distinct inventions. It is pointed out that the claim encompasses in terms of the final species/compound/composition of such Group XIII:

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Specie 1: the compound classified in class 514, subclass 675.

Specie 2: the compound classified in class 514, subclass 277.

Specie 3: the compound classified in class 514, subclass 645.

Specie 4: the compound classified in class 514, subclass 579.

Claims 187-207 drawn in Markush format encompass multiple and patentably distinct inventions. It is pointed out that the claim encompasses in terms of the final species/compound/composition of such Group XIV:

Specie 1: the compound classified in class 514, subclass 675.

Specie 2: the compound classified in class 514, subclass 277.

Specie 3: the compound classified in class 514, subclass 645.

Specie 4: the compound classified in class 514, subclass 579.

Claims 208-228 drawn in Markush format encompass multiple and patentably distinct inventions. It is pointed out that the claim encompasses in terms of the final species/compound/composition of such Group XV:

Specie 1: the compound classified in class 514, subclass 675.

Specie 2: the compound classified in class 514, subclass 277.

Specie 3: the compound classified in class 514, subclass 645.

Specie 4: the compound classified in class 514, subclass 579.

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The groups above are set forth in order of precedence in the claims. Any specie/compound/composition having the distinguishing feature set forth in one of the above groups will be contained in that group regardless of the fact that it may also contain a feature set forth in a group of lower precedence.

It is considered that at Markush type claim encompassing such species is directed to multiple independent and patentably distinct inventions since the species are so unrelated and diverse that a prior art reference anticipating the claims with respect to one of the species will not render the claim anticipated or obvious under 35 U.S.C. 102 nor 35 U.S.C. 103 respectively with regard to any one other of the species. Further these species are considered to be independent since they are unconnected in operation, one does not require the others for ultimate use and the specification does not disclose a dependent relationship between them. Moreover, each of the stated species is considered patentably distinct from the others on the basis of its properties. Thus, the stated species are capable of supporting separate patents under 35 U.S.C. 121.

Accordingly, applicants are required to make a provisional election of a single independent and /or patentably distinct species stated *supra* prior to an examination of said species on the merits. This election will be given effect in the event the Markush type claims are not found allowable, at which time the examination of the claims presented will be limited to the Markush type claims and claims directed solely to the elected species. The claims directed solely to the nonelected species will be held withdrawn from further consideration. It should be noted that an election of species has

been held to be tantamount to a requirement for restriction (see *In re Herrick*, 1958 CD 1, and *In re Joyce* 1958 CD2).

Applicant's response must include a provisional election of one of the independent and patentably distinct inventions identified above even though the requirement is traversed (37 C.F.R. 1.142 and 1.143). Applicant is advised that any traverse must be supported by argument in order to perfect the right to petition in the event that the provisional requirement is given effect in the event noted above.

Linking Claims

Claim 4 links the inventions of Groups I-IV, claim 51 links the inventions of Groups V-VIII and claim 98 links the inventions of Groups IX-XII. Claims 229-245 and 250-266 link the inventions of Groups I, V and IX, claims 229-244, 246, 250-265 and 267 link the inventions of Groups II, VI and X, claims 229-244, 247, 250-265 and 268 link the inventions of Groups III, VII and XI, claims 229-244, 249-265 and 270 are claims linking the Groups IV, VIII and XII and claim 248 links the inventions of Groups I-XV. Upon the allowance of the linking claim(s), the species election requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double

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patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Election

The following specie election is required also regarding the election of either of Groups III, IV, VII, VIII, XI, XII, or Specie 3 or Specie 4 of Groups XIII, XIV and XV, wherein Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant is required to define each of R, R¹, R², R³, R⁴, A, n and any additional variables as required for a particular species. Currently, claims 145-160 and 166-181 are generic for Group XIII, claims 187-202 are generic for Group XIV and claims 208-223 are generic for Group XV.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Election/Restrictions Proper

MPEP §809.02(d) states “[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary.”. Here, the claims recited such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

The present claims are directed to a method of treating various types of cancer. Present claim 3 for example provides a variety of possibilities for R^2 , R^3 , R^4 and n . For hypothetical exemplification purposes only, if each of the variables above were each limited to 10 possible moieties there would be 10^4 possible species of compounds to be searched.

Further, as shown by the following classifications, a majority of the combinations encompassed by the present claims has acquired a separate status in the art. For example, the compound of Group I contains a hydrocarbon ring and is classified in class

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514 subclass 675 whereas the compound of Group II contains a heteroaryl moiety and is classified in class 514 subclass 277. Similarly, the compounds are distinct between Groups I and III etc. Notwithstanding that the classification of some of the active agents is co-extensive, all of the claimed compounds are patently distinct and fully capable of supporting separate patents.

The inventions above are patentably distinct. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicated above is deemed proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4 September 2006
MG

 9/5/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER